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510(k) SUMMARY

AUG 26 2008

5.1 MANUFACTURER / REGISTRATION INFORMATION

MANUFACTURER NAME / LOCATION	ESTABLISHMENT REGISTRATION NUMBER
Lake Region Manufacturing, Inc. (d/b/a Lake Region Medical) 340 Lake Hazeltine Drive Chaska, MN 55318-1029 USA	2126666

5.2 SUBMITTER / CONTACT PERSON

Contact Person: Deep Pal
Title: Regulatory Affairs Specialist
Telephone: (952) 448-5111, Ext. 6381
Fax: (952) 448-3441
Email: dpal@lakergn.com

5.3 TRADE NAME (PROPRIETATY NAME)

Taxi® Endoscopic Guidewire

5.4 DEVICE COMMON NAMES/USUAL NAMES/CLASSIFICATION NAMES

These devices are commonly known as Guides, Guidewires, or Spring Guidewires. The current classification names and product codes are Endoscopic Guidewire, Gastroenterology-Urology (OCY).

5.5 CLASS OF DEVICE

This type of Guidewire is listed as a Class II device by the Gastroenterology / Urology Review Panel; OCY, Endoscope and accessories (21 CFR 876.1500).

5.6 PREDICATE DEVICE

510(k) NUMBER	MANUFACTURER	DEVICE NAME
K922302	Boston Scientific Corp.	Jagwire™ Recanalization Guidewire

5.7 DEVICE DESCRIPTION

The Taxi® Endoscopic Guidewire is a dual colored, spiral patterned guidewire. The guidewire is composed of a Nitinol core with a dual colored PTFE jacket applied over the core to provide endoscopic visualization of wire movement. A polyurethane/tungsten loaded jacket encapsulates the distal end and ensures radiopacity. The distal tip of the guidewire is coated with hydrophilic coating.

The guidewires are bound by the following parameters:

GUIDEWIRE DIAMETER	LENGTHS	TIP		COATING	
		CONFIGURATION	FLEX	PTFE	HYDRO
.035"	260 - 450cm	Straight	Standard	Shaft	Tip

(Continues...)

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510(k) SUMMARY

(Continued...)

5.8 TECHNOLOGICAL CHARACTERSTICS

The predicate device is constructed of a nitinol core, which is encapsulated in a stripped PTFE jacket and a polyurethane distal jacket with a hydrophilic radiopaque distal tip. The striped jacket provides endoscopically visible movement markings. The Taxi® Endoscopic Guidewire is constructed of similar materials but employs a gluing process to adhere the polyurethane segment.

5.9 APPLICABILITY OF PERFORMANCE STANDARDS

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.

5.10 INTENDED USE STATEMENT

The Endoscopic Guidewire is intended for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. The Endoscopic Guidewire is designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

5.11 COMPARISION INFORMATION

PROPOSED DEVICE TAXI® ENDOSCOPIC GUIDEWIRE	PREDICATE DEVICE JAGWIRE(TM) RECANALIZATION GUIDEWIRE K922302
CORE	
Nitinol	Nitinol
JACKET	
PROXIMAL - PTFE	PROXIMAL - PTFE
DISTAL – Polyurethane	DISTAL – Polyurethane
COATING	
DISTAL - Hydrophilic	DISTAL - Hydrophilic
JOINING AGENTS	
Polymer Adhesive / Accelerator	No known adhesives used.
VARIOUS TIP FLEXIBILITIES	
5CM Standard	5CM and 10CM
GUIDEWIRE LENGTHS	
260cm to 450cm	260 and 450CM
GUIDEWIRE DIAMETERS	
.035"	.025" and .035"
STERILIZATION METHOD	
ETO	ETO

(Continues...)

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(Continued...)

5.12 QUALIFICATION TESTING

NON-CLINICAL TESTS

In order to demonstrate the safety and effectiveness of the Taxi® Endoscopic Guidewire, LRM performed testing to established requirements. Test pieces were tested and inspected according to established specific inspection criteria requirements for visual/tactile, dimensional and mechanical attributes. The results of these tests demonstrated the functionality and performance characteristics of these Guidewires are comparable to the similar currently marketed devices.

BIOCOMPATIBILITY TESTING

Biocompatibility testing per ISO 10993 series has been performed on the Taxi® Endoscopic Guidewire and has been found to be acceptable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2008

Mr. Deep Pal
Regulatory Affairs Specialist
Lake Region Medical™
340 Lake Hazeltine Drive
CHASKA MN 55318-1029

Re: K081708
Trade/Device Name: Taxi® Endoscopic Guidewire
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: June 13, 2008
Received: June 17, 2008

Dear Mr. Pal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081708

INDICATIONS FOR USE

510(k) Number (if known): K081708

Device Name:
Taxi® Endoscopic Guidewire

Indications for Use:
The Endoscopic Guidewire is intended for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. The Endoscopic Guidewire is designed to be used during endoscopic biliary procedures for catheter introduction and exchanges of catheters, cannulas, and sphincterotomes.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081708